



# VAPHS Quarterly Research Review

WINTER EDITION

Volume 3, Issue 1

## Plans Underway for New Research Office Building

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The VA Pittsburgh Healthcare System continues its commitment to excellence in research as designs for the new Research Building are well underway. Scheduled to be completed and activated in Fiscal Year 2012, the new Research Building will consist of a total of 65,000 square feet of space within three levels and will have nearly 15,000 square feet of state of the art wet lab space. The building design also allows for future expansion, including plans for a new animal research facility addition in the near future. In addition to housing Research Administration, the new building will also be the home of Center for Health Equity Research and Promotion, Geriatric Research, Education and Clinical Center, Mental Illness Research, Education and Clinical Center, the new Bioinformatics Core and the VA Pittsburgh Healthcare System Clinical Trials Center. Ground preparation for the new building is expected to start at the end of 2009.

### Special Topics

- \* Changes to Research Education and Compliance Office (Page 3)
- \* Informed Consent Requirements (Page 5)
- \* Research Week 2009 (Page 5)

## IRB Submissions and Meeting Dates

### March

Submission Date:  
February 25

Meeting Date:  
March 23

### April

Submission Date:  
April 1

Meeting Date:  
April 27

### May

Submission Date:  
April 22

Meeting Date:  
May 18



## WELCOME

Please help us welcome the following new research staff members:

Keri Baker, Financial Compliance Officer for the

Research and Development Office. Ms. Baker holds a Bachelor's Degree in Accounting and is currently pursuing her Master's Degree in Business Administration. In her spare time, Keri volunteers with Animal Protectors of Allegheny Valley, and spends time with her two miniature pinschers, Sasha and Titus. Keri is also the Contracting Officer for the VAPHS Clinical Trials Center.

Jodi Roberts, BS, MAT, Clinical Research Coordinator for the Clinical Trials Center. Jodi comes to us with prior research experience working for the Hillman Cancer Center as a Research Associate and the Family Planning Research Center at Magee Women's Hospital as both a Senior Research Assistant and monitor. Jodi is also a mom to two boys. Her third "child" is a retired racing greyhound named Snoop.

Karen Thieroff has joined Shirley Podnar, Pharm D, as the Research Pharmacy Technician for the Investigational Drug Service (IDS). Karen has 15 years of pharmacy experience with the last eight years in Investigational Drugs at UPMC. She is also a proud grandmother.

## EDUCATIONAL SEMINARS



**MARCH:** The VAPHS HRPP Education Series is pleased to announce that our March session will feature special guest, Jeremy Sugarman, MD, MPH, MA. This session will be held on Monday, March 2nd from 12 –1 pm in the Building 8 Auditorium at Highland Drive.

Dr. Sugarman is the Harvey M. Meyerhoff Professor of Bioethics and Medicine, Professor of Medicine, Professor of Health Policy and Management, and the Deputy Director for Medicine of the Berman Institute of Bioethics at Johns Hopkins University. His work spans both theoretical and empirical research, focusing on issues related to informed consent and research ethics.

Dr Sugarman is a dynamic speaker and we encourage all members of the research community to attend this session.

Please be sure to RSVP to Stephanie Partee via email ([Stephanie.Partee@va.gov](mailto:Stephanie.Partee@va.gov)) or phone (412-954-5386) no later than Friday February 13th if you plan to attend. Shuttle service will be provided for those traveling from University Drive.

**APRIL:** Due to Dr. Sugarman's March presentation. The topic originally scheduled for April " Adverse Events and Unanticipated Problems" will not be presented. The April presentation will focus on "VAPHS Data Security and Privacy".

**MAY:** The education year officially ends on May 31, 2009, as such, the Education and Policy Office devotes the month of May to providing investigators and coordinators with the opportunity to "catch-up" on those sessions they may have missed. Please keep in mind that our local education policy requires that PI's of active, non-exempt human subjects research studies must attend 3 core education sessions between June 1, 2008 and May 31, 2009. Research coordinators / project managers must attend six education sessions, including at least three core education sessions, between June 1, 2008 and May 31, 2009. Those PI's without a research coordinator named on an active study are responsible for attending 6 education sessions. If you have questions regarding whether you have satisfied these requirements, please contact Stephanie Partee at 54-5386 or [Stephanie.Partee@va.gov](mailto:Stephanie.Partee@va.gov).

## RESEARCH EDUCATION AND COMPLIANCE OFFICE CHANGES

In October 2008, the VHA Office of Research and Development issued directive 2008-064 entitled, "Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations and Policies." In accordance with this directive, each VA facility that conducts human subject research must have a full-time Research Compliance Officer, whose primary function will be to complete both informed consent audits (for human subjects research) and regulatory audits, initially focusing on human subjects research, but eventually broadening to all other aspects of research. In order to comply with this directive, the Research Education and Compliance Office has undergone a few changes.



Tammy Capozzoli will serve as the facility's Research Compliance Officer. Tammy will be overseeing the facility's auditing program and her attention will be focused on ensuring that audits are completed, and that any serious or continuing non-compliance is appropriately reported.

Krissa Caroff has assumed the role of Research Education and Policy Coordinator. Ms. Caroff's responsibilities now include, overseeing and implementing the VAPHS Research Education Program, policy development, implementation, and dissemination, and serving as the Research Office's public affairs liaison.

Ms. Capozzoli and Ms. Caroff will both be working diligently in their new roles and are happy to take questions or concerns regarding their new responsibilities.

### TIPS FROM THE IRB OFFICE

1. PLEASE USE THE MOST RECENT VERSION OF THE TEMPLATES AND SUBMISSION FORMS. Always check the VAPHS Research Office Website prior to preparing your submission to ensure that you have the most recent version.
2. Submission materials must be signed and dated in order to be considered complete.
3. All consent forms and protocols should have a version date typed on them. This version date is the date that the document was created or modified by you. It is not the same as the version date that the template was created by the research office. Those dates should not be modified.
4. All submissions to the IRB Office must be made in paper format. E-mail submissions are not acceptable at this time.
5. If your protocol includes a Data Safety Monitoring Board (DSMB) or other independent monitoring body, a copy of the DSMB report **MUST** be submitted at the time of continuing review. If the DSMB did not meet as described in the protocol, a letter or some other documentation from the study sponsor or coordinating center must accompany your continuing review.
6. Submission deadlines for studies being reviewed by the fully convened IRB will be **strictly enforced**.
7. Please do not wait until submission day to deliver submissions to the Research Office. If at all possible, items should be submitted for review as soon as they are complete.



## FUNDING OPPORTUNITIES

### **Department of Defense (DoD) Ovarian Cancer Research Program \$20 Million:**

*The Department of Defense Ovarian Cancer Research Program (OCRP) has released the following program announcements for Idea Development Awards and Collaborative Translational Research Awards for FY2009.*

#### **DEADLINES:**

- Pre-Application (pre-proposal) through <http://cdmrp.org/> required and due: March 2, 2009; 5:00 pm EST
- Pre-proposal (above) is required; Application (full proposal) submission is by invitation only
- In response to invitation; Application must be submitted through <http://www.grants.gov/> and is due: June 2, 2009; 11:59 pm EST.

The Program Announcement and Application Instructions can be found at <http://cdmrp.army.mil/funding/ocrp.htm>

Synopsis Table: <http://cdmrp.army.mil/funding/pdf/09ocrpreftable.pdf>, pages 2 & 3.

### **DoD Prostate Cancer Research Program \$80 Million:**

*The Department of Defense Prostate Cancer Research Program (PCRP) has released two program announcements for Idea Development Awards and Synergistic Idea Development Awards for FY2009.*

#### **DEADLINES:**

**For both PCRP Idea Development Awards and Synergistic Idea Development Awards:**

- Pre-Application (including pre-proposal) through <http://cdmrp.org/> required and due: March 3, 2009; 5:00 pm EST
- Invitations for proposals will be issued in April, 2009.
- Only those invited to submit an Application (including full Proposal) may do so through <http://www.grants.gov/> due June 10, 2009, 11:59 p.m. EST.

### **DoD Neurofibromatosis Research Program \$10 Million:**

*The Department of Defense Neurofibromatosis Research Program (NFRP) has released program announcements for Investigator-Initiated Research Awards and Clinical Trial Awards.*

#### **DEADLINES:**

**For both NFRP Investigator-Initiated Research Awards and Clinical Trial Awards:**

- Pre-Application (Letter of Intent) through <http://cdmrp.org/> required and due: March 24, 2009; 5:00 pm EST
- Application including Proposal through <http://www.grants.gov/> due April 14, 2009, 11:59 p.m. Eastern Time.

Requests for e-mail notifications of the release of any of the above Program Announcements may be sent to **[help@cdmr.org](mailto:help@cdmr.org)**.

**ADDITIONAL  
FUNDING  
OPPORTUNITIES  
ARE PROVIDED  
ON PAGE 6**

## INFORMED CONSENT REQUIREMENTS

For human subjects' researchers, it's important to keep in mind, the following key points related to the informed consent process and documentation:

- All informed consent documents must be signed and dated by the subject, or his or her legally authorized representative (in cases where the IRB has granted the use of surrogate consent) use of a legally authorized representative
- The informed consent document signed by the subject must be the currently IRB approved version, and must have the IRB approval stamp, noting the consent version date, date approved, and expiration date, in the lower right hand corner of each page.
- No study procedures may be initiated prior to obtaining informed consent.
- A Health Insurance Portability and Accountability Act (HIPAA) Research Authorization signed by the subject must be used anytime you are using Protected Health Information for research. In most cases, the study consent

form contains the HIPAA Authorization language, however, there may be circumstances in which you may need a freestanding HIPAA Authorization (VA-Form 10-5345).

- Only individuals who have been approved by the IRB may administer informed consent. These individuals must be listed on the Form "Authorized Individuals to Administer Informed Consent" and also included on the Research Staff Form.

Compliance with these requirements will be audited as part of the Research Compliance Officer's Informed Consent Audits. Please note that failure to satisfy these requirements is considered non-compliance and is reportable to the Medical Center Director, VA Office of Research and Development (ORD), and to the VA Regional Office of Research Oversight (ORO).

If you have any questions about these requirements, please contact Ms. Capozzoli at 54-5388.



## MARK YOUR CALENDARS: RESEARCH WEEK 2009

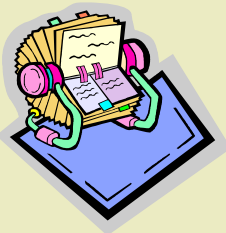
VA National Research Week will be celebrated May 3rd thru May 9th. This year's theme is "**VA Research: Turning Hope Into Reality.**"

This is an opportunity for all of us to highlight the great work we are doing here at VAPHS! We encourage any and all ideas that promote the education of veterans, the public, and the media about VA research and its impact on treating and preventing disease and disability.

In order to prepare for this year's event, we will be requesting the assistance of those of you in the research community. In the upcoming month we will begin to assemble a Research Week planning committee and ask that you consider either serving on the committee yourself, or sending a representative to serve. In addition, we would again, like to feature a veteran-research participant. This individual would be asked to give a 3-5 minute presentation about his or her experience as a research subject. If you have anyone in mind, please let us know. We will be sending out additional information soon, but please feel free to share any ideas or suggestions as soon as possible. Contact Person: Krissa Caroff







### **RESEARCH CONTACTS**

**Ali F. Sonel, MD,**  
954-5381 ACOS, R&D

**Shekhar Gandhi, PhD,**  
954-5397

Deputy ACOS, R&D

**Nicholas Squeglia,**  
954-5387 AO- R&D

VRFP, Executive Director CTC

**Elizabeth Toth,** 954-5382

IBC and IACUC  
Subcommittees,

Grant Submissions

**Shannon Reichel,** 954-5380

R&D Committee Program  
Support

**Kathleen Parks,** 954-5396

IRB Coordinator

**Linda Calgaro,** 954-5394

IRB Program Asst.

**Chris Brining,** 954-5401

Orders

**Charlene Simmons,** 954-  
5392

Contracts, Orders, and

Research Accounts

**Krissa Caroff,** 954-5384

Policy and Education  
Coordinator

**Tammy Capozzoli,** 954-5388

Compliance Officer

**Stephanie Partee,** 954-5386

Education and Compliance  
Assistant

**Keri Baker,** 954-5391

VRFP and CTC, Travel

## **Funding Opportunities (continued)**

### **FY09 DOD Peer Reviewed Medical Research Program**

The Fiscal Year 2009 (FY09) Defense Appropriations Act provides \$50 million to the Department of Defense Peer Reviewed Medical Research Program (PRMRP) to support scientifically meritorious proposals that may impact the field of research and/or patient care across a diverse range of diseases and disorders. Specifically, the FY09 PRMRP is soliciting research applications across the following 19 congressionally-directed topic areas: alcoholism research; autoimmune diseases; blood cancer; childhood asthma; drug abuse; epilepsy; kidney cancer; listeria vaccine for infectious diseases and cancer; lupus; mesothelioma; molecular signatures in tumors; neuroblastoma; osteoporosis and related bone disease; Paget's disease; pediatric cancer; polycystic kidney disease; social work research; tinnitus; and West Nile virus vaccine. Applications submitted to the FY09 PRMRP must address one of the topic areas listed above.

This program is administered by the U.S. Army Medical Research and Materiel Command through the Office of the Congressionally Directed Medical Research Programs (CDMRP). A summary of FY09 PRMRP funding opportunities is provided below. Detailed descriptions of each of the FY09 PRMRP funding mechanisms, evaluation criteria, and submission requirements can be found in the corresponding Program Announcement and Application Instructions & General Information. Each Program Announcement is available electronically for downloading from the Grants.gov website (<http://www.grants.gov>), the CDMRP website (<http://cdmrp.army.mil/funding/prmrp.htm>) and the CDMRP eReceipt Website (<https://cdmrp.org>).

#### **Submission Deadlines:**

##### *For Investigator-Initiated Research Awards*

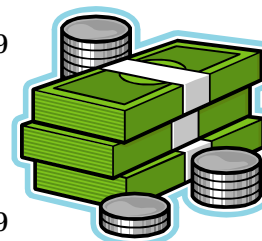
- Pre-Application Letter of Intent: March 19, 2009
- Application: April 16, 2009

##### *For Technology/Therapeutic Development Awards*

- Pre-Application Letter of Intent: March 19, 2009
- Application: April 16, 2009

##### *For Clinical Trial Awards*

- Pre-Application Letter of Intent: March 19, 2009
- Application: April 16, 2009



**ELECTRONIC SUBMISSIONS:** The VAPHS research submission and review process will soon be going electronic! We have chosen a system called IRBNet to manage all IRB, IA-CUC and IBC submissions. In the upcoming months we will be working to get all our forms loaded into the system. We hope to begin training investigators, staff, and committee members in late Spring and to launch the new system in mid-to late summer. If you would like more information regarding IRBNet, or would like to see an online demonstration, please visit [www.irbnet.org](http://www.irbnet.org).

**IRB LEADERSHIP:** Effective March 1st, Dr. Bruce Ling, will serve as chairperson of the VAPHS IRB. DR. Ling is an accomplished researcher and has served on the VAPHS IRB for a number of years in the past, regarded very highly by his peers. Both Dr. Dougherty and Dr. Fried will continue to serve as Vice-Chairpersons for the IRB. We thank Dr. Dougherty for all of his hard work as Acting Chair.

**NEW CLINICAL RESEARCH COORDINATOR REQUIREMENTS:** In an effort to ensure that we maintain the highest standards related to the research we conduct with our veterans, we will be issuing a new policy in the next few weeks that requires all clinical research coordinators currently employed at VAPHS be certified in their profession no later than June 30, 2010. The VAPHS recognizes two certification programs: The Certified Clinical Research Profession (CCRP) offered through the Society of Clinical Research Associates (SoCRA) or the Certified Clinical Research Coordinator (CCRC) offered through the Academy of Clinical Research Professionals. Please note that at this time this requirement

only applies to those coordinators who oversee clinical trials with interventions involving investigational drugs and/or devices. For additional information please contact, Nicholas Squeglia at 54-5387.



### **NEW PRESENTATION OF RESEARCH RESULTS**

**POLICY:** Effective February 2, 2009, the VAPHS Research and Development Office adopted a new policy regarding the presentation of research results. This new policy replaces the publication guidance formerly available on the Research Office website and is written based upon VHA Handbook 1200.19, Presentation of Research Results. Previous guidance had applied to only presentations and publications. The new policy is applicable to all forms of research results, including publications, in a scientific journal, as well as other activities resulting from the research, such as: presentations involving a national venue or the media; media interviews; and professional activities that involve a national venue or formal recognition, including awards (honors), committee or organizational appointments, and editorial board appointments. Please visit the VAPHS Research Office website at: <http://www.vaphs.research.med.va.gov/> for a copy of the new policy and associated forms.

**MICROSOFT OFFICE CONVERSION:** The VA will be converting from Microsoft Office 2003 to Microsoft Office 2007. The scheduled deadline to complete the conversion in Region 4 is July 31, 2009.



## **AWARDS AND RECOGNITION**

The following investigators have received funding since our last issue:

- **VISN 4 Competitive Pilot Project Fund (CPPF):** Dimitri Gutkin, MD; Dan Hall, MD; Scott Kulich, MD; Justin La Ferrier, Physical Therapist; Ronit Wollstein, MD
- **Biomedical Laboratory Research and Development (BLR&D):** Robert Sweet, MD
- The VA Pittsburgh Healthcare System has been awarded the 2011 bid for the National Veterans Wheelchair Games. For more information, the VAPHS Wheelchair Games office is located at the Highland Drive Division, Building #1, 4th Floor, Room A4080E. Telephone number 412-954-4834.
- Dr. Rory Cooper is leading a project entitled "The Personal Mobility and Manipulation Appliance (PerMMA)" which is featured on Carnegie Mellon University's Robotics Institute web site: <http://www.ri.cmu.edu/>
- Dr. Rajiv Jain, VAPHS Chief of Staff and VHA MRSA Prevention Initiative Program Director, received the 2008 Service to America award in the category of Citizen Services.
- Gerald Goldstein, Ph.D., will be receiving the International Neuropsychological Society's Distinguished Career Award at its meeting in Atlanta on Wednesday, February 11th, 2009.



## VAPHS Publications

*Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: A randomized controlled trial.* Weiner DK, Perera S, Rudy TE, Glick RM, Shenoy S, Delitto A. Pain. 2008 Nov 30;140(2):344-57. Epub 2008 Oct 17.

*Design of Combination Angiotensin Receptor Blocker and Angiotensin-Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy (VA-NEPHRON-D).* Fried LF, Duckworth W, Zhang JH, O'Connor T, Brophy M, Emanuele N, Huang GD, McCullough PA, Palevsky PM, Seliger S, Warren SR, Peduzzi P; for VA NEPHRON-D Investigators. Clinical Journal of the American Society of Nephrology. 2008 Dec 31. [Epub ahead of print]

*A perspective on intelligent devices and environments in medical rehabilitation.* Cooper RA, Dicianno BE, Brewer B, LoPresti E, Ding D, Simpson R, Grindle G, Wang H. Medical Engineering and Physics. 2008 Dec;30(10):1387-98. Epub 2008 Nov 6

*The impact of race and ethnicity on receipt of family planning services in the United States.* Borrero S, Schwarz EB, Creinin M, Ibrahim S. Journal of Women's Health (Larchmont). 2009 Jan-Feb;18(1):91-6.

*Design, development, and testing of a low-cost electric powered wheelchair for India.* Pearlman J, Cooper R, Chhabra HS, Jefferds A. Disability and Rehabilitation: Assistive Technology. 2009 Jan;4(1):42-57.

*Change in cardiovascular risk factors with progression of kidney disease.* Fried LF, Katz R, Cushman M, Sarnak M, Shlipak MG, Kuller L, Newman AB. American Journal of Nephrology. 2008 Oct 24;29(4):334-341.

*Trends and issues in wheelchair technologies.* Cooper RA, Cooper R, Boninger ML. Assistive Technology. 2008 Summer;20(2):61-72.

*Acute mountain sickness in disability and adaptive sports: preliminary data.* Dicianno BE, Aguila ED, Cooper RA, Pasquina PF, Clark MJ, Collins DM, Fitzgerald SG, Wichman TA. Journal of Rehabilitation Research & Development. 2008;45(4):479-87.

*Rehabilitation and medical management of the adult with spina bifida.* Dicianno BE, Kurowski BG, Yang JM, Chancellor MB, Bejjani GK, Fairman AD, Lewis N, Sotirake J. American Journal of Physical Medicine and Rehabilitation. 2008 Dec;87(12):1027-50.

*Longitudinal association of anthropometry with mammographic breast density in the Study of Women's Health Across the Nation.* Reeves KW, Stone RA, Modugno F, Ness RB, Vogel VG, Weissfeld JL, Habel LA, Sternfeld B, Cauley JA. International Journal of Cancer. 2009 Mar 1;124(5):1169-77.

*The Prostate cancer Intervention Versus Observation Trial: VA/NCI/AHRO Cooperative Studies Program #407 (PIVOT): design and baseline results of a randomized controlled trial comparing radical prostatectomy to watchful waiting for men with clinically localized prostate cancer.* Wilt TJ, Brawer MK, Barry MJ, Jones KM, Kwon Y, Gingrich JR, Aronson WJ, Nsouli I, Iyer P, Cartagena R, Snider G, Roehrborn C, Fox S. Contemporary Clinical Trials. 2009 Jan;30(1):81-7. Epub 2008 Aug 23.



## VAPHS Publications

*Consensus guidelines for oral dosing of primarily renally cleared medications in older adults.* Hanlon JT, Aspinall SL, Semla TP, Weisbord SD, Fried LF, Good CB, Fine MJ, Stone RA, Pugh MJ, Rossi MI, Handler SM. J Am Geriatr Soc. 2008 Dec 10. [Epub ahead of print]

*Longitudinal progression of negative symptoms in schizophrenia: a new look at an old problem.* Kelley ME, Haas GL, van Kammen DP. Schizophrenia Research. 2008 Oct;105(1-3):188-96. Epub 2008 Jul 11.

*Semantic memory in schizophrenia: association with cell membrane essential fatty acids.* Condray R, Yao JK, Steinhauer SR, van Kammen DP, Reddy RD, Morrow LA. Schizophrenia Research. 2008 Nov;106(1):13-28. Epub 2008 Oct 16.

*Heterogeneity of neuroendocrine stress responses in aging rat strains.* Segar TM, Kasckow JW, Welge JA, Herman JP. Physiology and Behavior. 2009 Jan 8;96(1):6-11. Epub 2008 Aug 5

*Reduced dendritic spine density in auditory cortex of subjects with schizophrenia.* Sweet RA, Henteloff RA, Zhang W, Sampson AR, Lewis DA. Neuropsychopharmacology. 2009 Jan;34(2):374-89. Epub 2008 May 7.

*An automated segmentation methodology for quantifying immunoreactive puncta number and fluorescence intensity in tissue sections.* Fish KN, Sweet RA, Deo AJ, Lewis DA. Brain Research. 2008 Nov 13;1240:62-72. Epub 2008 Sep 3.

*The relationship of excess cognitive impairment in MCI and early Alzheimer's disease to the subsequent emergence of psychosis.* Weamer EA, Emanuel JE, Varon D, Miyahara S, Wilkosz PA, Lopez OL, Dekosky ST, Sweet RA. International Psychogeriatrics. 2009 Feb;21(1):78-85. Epub 2008 Sep 25.

*Subdivisions of primary motor cortex based on cortico-motoneuronal cells.* Rathelot JA, Strick PL. Proceedings of the National Academy of Sciences U S A. 2009 Jan 20;106(3):918-23. Epub 2009 Jan 12.

*Altar and table: A phenomenology of the surgeon-priest.* Hall DE. Yale Journal of Biology and Medicine. 2008 Dec;81(4):193-8.

*Citalopram augmentation of subsyndromal symptoms of depression in middle-aged and older outpatients with schizophrenia and schizoaffective disorder.* A randomized controlled trial. Zisook S, Kasckow JW, Golshan S, Fellows I, Solorzano E, Lehman D, Mohamed S, Jeste DV. Journal of Clinical Psychiatry. 2008 Dec 23. [Epub ahead of print]

*Race, ethnicity and length of hospital stay after knee or hip arthroplasty.* Ibrahim, Said A ; Stone, Roslyn A; Cohen, Peter Z ; Henderson, William G ; Khuri, Shukri F ; Kwok, C Kent Current Orthopaedic Practice. 19(5):556-563, September 2008.

## VAPHS PRESENTATIONS

*Taking the perspective of the other: A behavioral observational study of social cognition and receptive communication deficits in schizophrenia and bipolar disorder.* Haas G, Valenti L, Luther J, Paldino D, Goldstein G. Presented at the Society for Research in Psychopathology Annual Meeting (September 2008).

